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August 23, 2010

Via ECF

Honorable Dennis M. Cavanaugh, USDJ
United States District Judge
United States District Court
Martin Luther King Building & U.S. Court House
Newark, New Jersey 07101

Re: Eli Lilly v. Actavis Elizabeth, et als.
Civil Action No. 07-3770 (DMC)

Dear Judge Cavanaugh:

This firm, along with Rockey, Depke & Lyons, LLC in Chicago, represents Sandoz Inc. in the above-referenced action. We respectfully request that the Court enter Final Judgment under Rule 54(b). We have attached a copy of Sandoz's proposed form of judgment for the Court's review.

I. This Court Should Enter Judgment as to Only the Defendants who Tried the Case

Rule 54(b) of the Federal Rules of Civil Procedure expressly provides that a Court may direct entry of a final judgment "as to one or more, but fewer than all, claims or parties" if the Court expressly determines that there is no just reason for delay. The judgment proposed by Sandoz is a judgment as to fewer than all of the parties to the above action. The only parties that are entitled to a judgment at the present time are those who participated in the trial of the action,

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namely Sun Pharmaceutical Industries Ltd., Sandoz Inc., Mylan Pharmaceuticals Inc., Apotex Inc. and Aurobindo Pharma Ltd., for the reasons set forth below.

Defendant Zydus Pharmaceuticals, USA, Inc., consented to a judgment that the '590 patent was not invalid (D.E. 105) while defendant Glenmark Pharmaceuticals, Inc., USA consented to a judgment that it did not rebut the presumption of validity of the '590 patent (D.E. 174). Defendant Synthron Laboratories, Inc., entered into a stipulation by which it withdrew its ANDA and hence was no longer a party to the case (D.E. 215). Those three defendants are not proper parties to the judgment in this case because a judgment in their favor would be inconsistent with their stipulations.

The same is true for defendants Teva Pharmaceuticals USA, Inc. ("Teva") and Actavis Elizabeth LLC ("Actavis"). Teva and Actavis entered into stipulations by which the cases against them were stayed. The Teva stipulation provides (D.E. 557, p. 3, ¶ 2):

" . . . all of Lilly's claims against Teva and Teva's defenses are stayed until a final court decision from which no appeal has been or can be taken, including any petition for a writ of certiorari to the U.S. Supreme Court or subsequent appeal."

The Actavis stipulation reads the same (D.E. 567, p.3, ¶ 2).

The stipulations between Lilly and Teva and Lilly and Actavis remain binding upon them. A case in point is Waldorf v. Shuta, 142 F.3d 601, 613 (3d Cir. 1998). In Waldorf, one of the parties, the Borough of Kenilworth, stipulated in open court as to liability. Waldorf, 142 F.3d at 612. When the Borough of Kenilworth tried to withdraw that stipulation, the Court refused, finding that the Borough:

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"... [E]ntered into the stipulation 'as a tactical decision that the amount of damages awarded to Waldorf, if any, would be of a lesser quantum if the jury awarding the damages was not aware of the Borough's actions leading to its liability'".

Waldorf, 142 F.3d at 614.

So, too, in this case. Teva and Actavis made "a tactical decision" and elected to not participate in the trial but rather await entry of a final non-appealable judgment. They must be held to those stipulations.

And, of course, both Teva and Actavis enjoyed the benefits of their stipulations, avoiding the time and expense of the trial. But now, Teva and Actavis ask this Court to ignore the language of the stipulations that sets forth the timing of the end of the stay of their cases, and, as a consequence, the timing of the entry of judgment in their favor. As noted above, the stay ends as to Actavis and Teva only when there is "a final court decision from which no appeal has been or can be taken." There can be no judgment entered on behalf of a party whose case is stayed. Thus, the stay against Actavis and Teva must remain in effect until the completion of any appellate proceedings, after which they may be entitled to a judgment in their favor.

The position now advocated by Teva and Actavis grants them a more favorable position than the one to which they previously agreed when they entered into their stipulations. The "price" for saving the resources they would otherwise have devoted to the trial was the delay in lifting the stay, and consequential entry of judgment, until after the appellate process concluded. That time has not yet come. Permitting Actavis and Teva to re-visit the terms of their stipulations based upon the success of the defendants who did invest their resources in the trial is unfair to the defendants who tried the case.

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Actavis has suggested (D.E. 672) that excluding Teva and Actavis from the judgment in effect amounts to a holding that the patent is invalid as to the parties who tried the case but valid as to Teva and Actavis. But that is not so. Under Blonder-Tongue Labs, Inc. v. University of Illinois Foundation, 402 U.S. 313, 349-50 (1971), the Supreme Court held that once a patent is found invalid, a patentee is collaterally estopped from asserting that patent as against anyone else. But the legal theory precluding any assertion of the '590 patent against Teva or Actavis is separate and apart from any judgment entered in this case.

Under Blonder-Tongue, Eli Lilly and Company is collaterally estopped from seeking to enforce its patent against anyone else. Under the stipulations, however, the '590 patent could not be enforced against either Teva or Actavis for the further reason that the action as to those defendants is stayed and will remain stayed until there is a final non-appealable judgment. And that has not yet occurred. Thus, the stay in fact precludes Lilly from enforcing the patent against Teva and Actavis. Teva and Actavis are not, as Actavis suggested, "in the same position as the other defendants in this case" (D.E. 672, p. 1). Teva and Actavis are in a far different position; the Lilly claims against them are stayed.

For all of the foregoing reasons, this Court should enter a final judgment under Rule 54(b) as to the defendants who tried the case. That judgment should not include Teva or Actavis since the action against those two defendants, pursuant to the stipulations with Lilly, are stayed until a final, non-appealable judgment is entered.

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II. This Court Should Expressly Find that there is No Just Reason for Delay in Entering Judgment

Rule 54(b) of the Federal Rules of Civil Procedure expressly states that this Court may enter judgment on fewer than all claims or as to fewer than all parties. Gentry v. Township of Gloucester, 736 F.Supp. 1322, 1327 (D.N.J. 1990). Two conditions must be met, namely that the judgment is "final" and that this Court expressly determine "that there is no just reason for delay". Those two conditions are satisfied here.

Elementary is the principle that the defendants who tried this case are, consistent with the purpose of the Hatch-Waxman Act, entitled to entry of a judgment. As this Court knows, entry of judgment here allows defendants who have secured tentative approval of their ANDAs to obtain final approval of their ANDA products and begin providing the public with less expensive generic drugs. Sanofi-Aventis U.S. LLC v. Sandoz, Inc., 2009 WL 1968900, *4 (D.N.J. 2009). There can be no doubt here that this case is ripe for entry of a final judgment under Rule 54(b). Indeed, a District Court's judgment is final where it "ends the litigation on the merits and leaves nothing for the court to do but execute the judgment" (Catlin v. United States, 324 U.S. 229, 233 (1945)).

As the Federal Circuit noted in W.L. Gore & Associates, Inc. v. International Medical Prosthetics Research Associates, Inc., 975 F.2d 858, 863 (Fed.Cir. 1992):

"Because the infringement claim and several dispositive defenses were ruled upon, the district court's judgment was

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final. The district court's act of bifurcating the misuse defense does not and cannot impact on the finality of its judgment."

Here, this Court decided the infringement issue on summary judgment and ruled on all four invalidity defenses, rejecting three and adopting one. That makes the judgment final.

That leaves, as the only remaining task for this Court, an express determination that there is no just reason for delay in entry of the judgment. Safetcare Manufacturing, Inc. v. Tele-Made, Inc., 497 F.3d 1262, 1267 (Fed. Cir. 2007). Certainly the stay of the case as to Teva and Actavis provides no reason to delay entry of judgment as to the defendants who tried the case. Indeed, that is precisely what their respective stipulations contemplate, namely, that those two defendants could avoid the trial and abide by whatever final, non-appealable judgment resulted. Clearly, there is no reason for delay in the entry of judgment as to the defendants who tried the case.

Sandoz respectfully requests that the Court to enter its proposed judgment.

Respectfully submitted,

/s/Eric I. Abraham
ERIC I. ABRAHAM

cc: All Counsel of Record via ECF

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY,

Plaintiff,

v.

ACTAVIS ELIZABETH LLC,
GLENMARK PHARMACEUTICALS
INC., USA, SUN PHARMACEUTICAL
INDUSTRIES LIMITED, SANDOZ INC.,
MYLAN PHARMACEUTICALS INC.,
APOTEX INC., AUROBINDO PHARMA
LTD., TEVA PHARMACEUTICALS
USA, INC., SYNTHON
LABORATORIES, INC., ZYDUS
PHARMACEUTICALS USA, INC.,

Defendants.

Civil Action No. 07-3770 (DMC)

**FINAL JUDGMENT UNDER
RULE 54(b)**

This matter having come before the Court on a complaint by plaintiff, Eli Lilly and Company, for infringement of U.S. Patent No. 5,658,590 ("the '590 patent") against defendants, Actavis Elizabeth LLC, Glenmark Pharmaceuticals Inc., USA, Sun Pharmaceutical Industries Limited, Sandoz Inc., Mylan Pharmaceuticals Inc., Apotex Inc., Aurobindo Pharma Ltd., Teva Pharmaceuticals USA, Inc., Synthon Laboratories, Inc., and Zydus Pharmaceuticals USA, Inc.;

Defendant Zydus Pharmaceuticals USA, Inc., having consented to a judgment that the '590 patent was not invalid, defendant Glenmark Pharmaceuticals Inc., USA, having consented to a judgment that it did not rebut the presumption of validity of the '590 patent and defendant Synthon Laboratories, Inc., having consented to a judgment in which it withdrew its ANDA;

This Court having determined on a motion for summary judgment that defendants Actavis Elizabeth LLC, Sun Pharmaceutical Industries Limited, Sandoz Inc., Mylan Pharmaceuticals Inc., Apotex Inc., Aurobindo Pharma Ltd., and Teva Pharmaceuticals USA, Inc., have induced infringement of the '590 patent;

Defendants Teva Pharmaceuticals USA, Inc., and Actavis Elizabeth LLC having acknowledged and agreed that the '590 patent would be infringed by manufacture, use, sale, offer to sell, importation or distribution of atomoxetine tablets pursuant to ANDA nos. 79-022 and 78-940, respectively;

Defendants Teva Pharmaceuticals USA, Inc., and Actavis Elizabeth LLC, having stipulated to stay the action pending a non-appealable decision and this Court having so ordered;

The matter having come before the Court for trial on the merits of all remaining issues between plaintiff Eli Lilly and Company and defendants Sun Pharmaceutical Industries Limited, Sandoz Inc., Mylan Pharmaceuticals Inc.,

Apotex Inc., and Aurobindo Pharma Ltd. ("the Trial Parties"), to determine whether all of the claims of the '590 patent are invalid and/or unenforceable by reason of (i) obviousness; (ii) inequitable conduct; (iii) lack of enablement to the full scope of the claims of the patent; and (iv) lack of enablement utility; and the Court having heard testimony of the witnesses of the Trial Parties and having considered documentary evidence and depositions of all of those Trial Parties and having reviewed the pretrial and post trial submissions by the Trial Parties and having heard closing arguments by the Trial Parties; and based on the findings of view and conclusions of law set forth in the court's opinion of August 12, 2010;

IT IS ON THIS _____ DAY OF AUGUST, 2010, ORDERED,
ADJUDGED AND DECREED as to plaintiff Eli Lilly and Company and
defendants Sun Pharmaceutical Industries Limited, Sandoz Inc., Mylan
Pharmaceuticals Inc., Apotex Inc., and Aurobindo Pharma Ltd., that:

- (1) Defendants Sun Pharmaceutical Industries Limited, Sandoz Inc., Mylan Pharmaceuticals Inc., Apotex Inc., and Aurobindo Pharma Ltd., have induced infringement of claims 1-16 of the '590 patent;
- (2) Claims 1-16 of the '590 patent are invalid for lack of enablement in the disclosure of utility under 35 USC § 112;
- (3) Claims 1-16 of the '590 patent are not unenforceable by reason of inequitable conduct;

- (4) Claims 1-16 of the '590 patent are not invalid for obviousness and
- (5) Claims 1-16 are not invalid for lack of enablement over the full scope of the claims.

Defendants Teva Pharmaceuticals USA, Inc. and Actavis Elizabeth LLC, having reached stipulations with Eli Lilly that all of Lilly's claims and their defenses are stayed pending a non-appealable decision, the Court finds that there is no just reason for delay and enters judgment as to defendants Sun Pharmaceutical Industries Limited, Sandoz Inc., Mylan Pharmaceuticals Inc., Apotex Inc., and Aurobindo Pharma Ltd. under Rule 54(b) of the Federal Rules of Civil Procedure.

Honorable Dennis M. Cavanaugh
United States District Judge